IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN

ABBOTT LABORATORIES and ABBOTT RESPIRATORY LLC,	)	
Plaintiffs,	)	C.A. No. 2:10-cv-10656
v.	)	
SUN PHARMACEUTICAL INDUSTRIES, LTD. and SUN PHARMA GLOBAL FZE,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Abbott Laboratories and Abbott Respiratory LLC (collectively, "Abbott"), by their attorneys, hereby allege as follows:

Nature of the Action

This is an action for patent infringement of U.S. Patent Nos. 6,080,428 ("the '428 patent") and 6,469,035 ("the '035 patent"), arising under the patent laws of the United States, Title 35, United States Code, 35 U.S.C. §§ 271 and 281. This action relates to Abbreviated New Drug Application ("ANDA") No. 20-0484 filed by Sun Pharma Global FZE ("Sun FZE") with the U.S. Food and Drug Administration ("FDA") for approval to market 500 mg and 1000 mg niacin extended-release tablets that are generic versions of the 500 mg and 1000 mg strength versions of Abbott's highly successful NIASPAN® drug product.

Related Actions

The present action is related to an identical patent infringement action pending before the United States District Court for the District of Delaware, *Abbott Laboratories and Abbott*

Respiratory, LLC v. Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceuticals, Inc. (C.A. 10-cv-112) (the "Delaware Sun Action"), pertaining to ANDA No. 20-0484 filed by Sun FZE for approval to market generic versions of Abbott's 500 mg and 1000 mg strength NIASPAN® tablets. The Delaware Sun Action was filed on February 12, 2010 and has not yet been assigned.

The present action also relates to an action for infringement of the '428 patent (and six other patents) pending before Judge Joseph Farnan in the United States District Court for the District of Delaware, *Abbott Laboratories, et al.. v. Lupin Limited, et al.* (C.A. No. 09-152) (the "Delaware Lupin Action"), pertaining to ANDA Nos. 90-446, 90-860, and 90-892 filed by Lupin for approval to market generic versions of NIASPAN®. The present action also relates to an action for infringement of the '428 and '035 patents pending before Judge Sue Robinson in the United States District Court for the District of Delaware, *Abbott Laboratories, et al. v. Teva Pharmaceutical Industries, Ltd., et al.* (C.A. No. 10-57) (the "Delaware Teva Action"), pertaining to ANDA No. 200478 filed by Teva for approval to market a generic version of Abbott's cholesterol drug SIMCOR®.

Parties

1. Abbott Laboratories is a corporation organized and existing under the laws of the State of Illinois, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

2. Abbott Respiratory LLC ("Abbott Respiratory") is a limited liability corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

3. Upon information and belief, Defendant Sun Pharmaceutical Industries Ltd. ("Sun Ltd.") is a company organized and existing under the laws of India with a place of business at

Acme Plaza, Andheri-Kurla Road, Andheri (East), Mumbai-400 059, India. Upon information and belief, Sun Ltd. manufactures numerous generic drugs, including the generic drugs that are the subject of ANDA No. 20-0484, for sale and use throughout the United States, including in this judicial district.

4. Upon information and belief, Defendant Sun FZE is a company organized and existing under the laws of the United Arab Emirates with a principal place of business at Executive Suite # 43, Block Y, SAIF Zone, P.O. Box 122304, Sharjah, U.A.E. Upon information and belief, Sun FZE is a wholly-owned subsidiary of Sun Pharma Global Inc., a company incorporated under the laws of the British Virgin Islands, which is a wholly-owned subsidiary of Sun Ltd.

5. Upon information and belief, Defendants Sun Ltd. and Sun FZE (collectively, "Defendants" or "Sun") acted collaboratively in the development of the generic products that are the subject of ANDA 20-0484 and in the preparation and submission of ANDA 20-0484. Upon information and belief, Sun FZE's preparation and submission of ANDA 20-0484 was done at the direction, under the control, and for the direct benefit of Sun Ltd.

6. Upon information and belief, and consistent with its practice with respect to other generic products, following any FDA approval of ANDA No. 20-0484, Sun will sell its generic product throughout the United States.

Jurisdiction and Venue

7. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

8. This Court has personal jurisdiction over each of the Defendants because, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, a tortious act of patent infringement in filing ANDA No. 20-0484 that has led to foreseeable harm and injury to a corporation actively engaged in business in Michigan, Abbott Laboratories**.**

9. This Court also has personal jurisdiction over each of the Defendants by virtue of, *inter alia*, their systematic and continuous contacts with Michigan as set forth below, and for other reasons that will be presented to the Court if jurisdiction is challenged.

10. This Court has personal jurisdiction over Defendant Sun Ltd. by virtue of its systematic and continuous contacts with Michigan through its wholly-owned subsidiary and agent, Sun Pharmaceutical Industries, Inc. ("Sun Inc."). Sun Inc. is a company organized existing under the laws of the State of Michigan with a principal place of business at 270 Prospect Plains Road, Cranbury, NJ 08512. Upon information and belief, Sun Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district. Upon information and belief, Sun Ltd. maintains a website, http://www.sunpharma.com, which states that: "Sun Pharmaceutical Industries Inc is a Michigan Corporation and a wholly owned subsidiary of Sun Pharmaceutical Industries Ltd, India."

11. This Court also has personal jurisdiction over Defendant Sun Ltd. by virtue of its systematic and continuous contacts with Michigan through its affiliate, Caraco Pharmaceutical Laboratories, Ltd. ("Caraco"). Upon information and belief, Sun Ltd. is Caraco's majority shareholder. Caraco is a company organized and existing under the laws the State of Michigan with a principal place of business at 1150 Elijah McCoy Drive, Detroit, MI 48202. Upon information and belief, Caraco manufactures numerous generic drugs for sale and use throughout

the United States, including this judicial district. Upon information and belief, Caraco maintains a website (http://www.caraco.com), which states:

> In 1997, Sun became Caraco's majority shareholder, and subsequently, the two companies entered into a technology transfer agreement. . . Sun agreed to transfer the technology for 25 products . . . which Caraco would file with the FDA. Also, Caraco has recently entered into a definitive agreement to market Sun ANDAs that are either approved or awaiting approval at the FDA.

Upon information and belief, Sun Ltd. maintains a website (http://www.sunpharma.com), which states that Sun Ltd.'s stake in Caraco "is 75% on a diluted basis, which has been reached by technology transfer" and:

> Based on the technology transferred out of Sun Pharma, Caraco now markets 34 ANDAs (including 10 Sun Pharma ANDAs) and has witnessed an increase in sales to $117 million in the year ending March 2007. 77 more ANDAs await approval from both companies with a well-considered pipeline of generics under development. The US generic opportunity is immense, with products worth over $40 bil likely to go off patent in the next few years. For some key products, Caraco sources API from Sun Pharma's plants and competes as an integrated manufacturer.

12. Defendant Sun Ltd. has availed itself of the legal protections of the State of Michigan by affirmatively filing suit in the United States District Court for the Eastern District of Michigan. *See Sun Pharmaceutical Industries Ltd. v. Eli Lilly and Co.* (C.A. 2:07-15087) (E.D. Mich.). Defendant Sun Ltd. has further availed itself of the legal protections of the State of Michigan by filing counterclaims in lawsuits filed in the United States District Court for the Eastern District of Michigan, including *Abbott Labs. v. Sun Pharmaceutical Industries, Ltd.* (C.A. 08-10498) (E.D. Mich.); *PDL Biopharma, Inc. v. Sun Pharmaceutical Industries Ltd.*, (C.A. 4:07-11709) (E.D. Mich.); and *Sanofi-Aventis U.S. LLC, et al. v. Sun Pharmaceutical Industries Ltd., et al.* (C.A. 2:07-13107) (E.D. Mich.).

13. In previous litigations, Defendant Sun Ltd. has consented to, and admitted that it is subject to, personal jurisdiction in the Eastern District of Michigan. *See Sanofi-Aventis U.S. LLC, et al. v. Sun Pharmaceutical Industries Ltd., et al.* (C.A. 2:07-13107) (E.D. Mich.).

14. The Court has personal jurisdiction over Defendant Sun FZE by virtue of its systematic and continuous contacts with Michigan, including through its parent corporation, Sun Ltd., and its sibling corporations, Sun Inc. and Caraco.

Patents in Suit

15. Abbott Respiratory is the owner by assignment of the '428 patent, entitled "Nicotinic Acid Compositions for Treating Hyperlipidemia and Related Methods Therefor," which the U.S. Patent and Trademark Office duly and legally issued on June 27, 2000. A true and correct copy of the '428 patent is attached hereto as Exhibit A. The claims of the '428 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the '428 patent with respect to NIASPAN®, with the right to sue for and obtain equitable relief and damages for infringement of the '428 patent.

16. Abbott Respiratory is the owner by assignment of the '035 patent, entitled "Methods of Pretreating Hyperlipidemic Individuals with a Flush Inhibiting Agent Prior to the Start of Single Daily Dose Nicotinic Acid Therapy to Reduce Flushing Provoked by Nicotinic Acid," which the U.S. Patent and Trademark Office duly and legally issued on October 22, 2002. A true and correct copy of the '035 patent is attached hereto as Exhibit B. The claims of the '035 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the '035 patent with respect to NIASPAN®, with the right to sue for and obtain equitable relief and damages for infringement of the '035 patent.

17. Abbott Laboratories is the holder of New Drug Application ("NDA") No. 20-0381 by which the FDA granted approval for 500 mg, 750 mg and 1,000 mg strength niacin extended-release tablets, which Abbott markets in the United States under the trade name "NIASPAN®". The formulation and dosing of NIASPAN® is covered by certain claims of the '428 patent and the '035 patent. The FDA's official publication of approved drugs (the "Orange Book") includes NIASPAN® together with the '428 patent and the '035 patent.

Infringement by Sun

18. By letter dated January 4, 2010 ("the Notice Letter"), Sun notified Abbott that Sun had submitted ANDA No. 20-0484 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, and sale of generic niacin extended-release tablets before the expiration of the '428 and '035 patents. Upon information and belief, Sun intends to engage in commercial manufacture, use, and sale of generic niacin extended-release tablets promptly upon receiving FDA approval to do so.

19. By filing ANDA No. 20-0484, Sun has necessarily represented to the FDA that the components of its generic niacin extended-release tablets have the same active ingredients as those of the corresponding components of NIASPAN®, have the same route of administration, dosage form, and strengths as the corresponding components of NIASPAN®, and are bioequivalent to the corresponding components of NIASPAN®.

20. In the Notice Letter, Sun notified Abbott that its ANDA contained a "Paragraph IV certification" asserting that, in Sun's opinion, the '428 patent and the '035 patent are invalid and/or will not be infringed by the commercial manufacture, use or sale of its generic niacin extended-release tablets.

21. This Complaint is being filed before the expiration of the forty-five days from the date Abbott received the Notice Letter.

Count I (Infringement of the '428 Patent)

22. Each of the preceding paragraphs 1 to 21 is incorporated as if fully set forth.

23. Sun's submission of ANDA No. 20-0484 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release tablets prior to the expiration of the '428 patent constitutes infringement of one or more of the claims of the '428 patent under 35 U.S.C. § 271(e)(2)(A).

24. Upon FDA approval of Sun's ANDA No. 20-0484, Sun will further infringe the '428 patent by making, using, offering to sell, and selling generic niacin extended-release tablets in the United States and importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

25. Upon information and belief, Sun had actual and constructive knowledge of the '428 patent prior to filing ANDA No. 20-0484 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '428 patent.

26. If Sun's infringement of the '428 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

Count II (Infringement of the '035 Patent)

27. Each of the preceding paragraphs 1 to 26 is incorporated as if fully set forth.

28. Sun's submission of ANDA No. 20-0484 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release tablets

prior to the expiration of the '035 patent constitutes infringement of one or more of the claims of the '035 patent under 35 U.S.C. § 271(e)(2)(A).

29. Upon FDA approval of Sun's ANDA No. 20-0484, Sun will further infringe the '035 patent by making, using, offering to sell, and selling generic niacin extended-release tablets in the United States and importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

30. Upon information and belief, Sun had actual and constructive knowledge of the '035 patent prior to filing ANDA No. 20-0484 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '035 patent.

31. If Sun's infringement of the '035 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

Prayer for Relief

WHEREFORE, Abbott prays that this Court grant the following relief:

a) A judgment that one or more claims of the '428 patent and the '035 patent are infringed by Sun's submission of ANDA No. 20-0484, and that Sun's making, using, offering to sell, or selling in the United States, or importing into the United States, of generic niacin extended-release tablets will infringe the '428 patent and the '035 patent;

b) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 20-0484 shall be a date which is not earlier than the latest expiration date of the '428 patent or the '035 patent, including any extensions and/or additional periods of exclusivity to which Abbott is or becomes entitled;

c) An order permanently enjoining Sun, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States generic niacin extended-release tablets until after the latest expiration date of the '428 patent and the '035 patent, including any extensions and/or additional periods of exclusivity to which Abbott is or becomes entitled;

d) Damages or other monetary relief to Abbott if Sun engages in commercial manufacture, use, offer to sell, sale, or importation in or into the United States of generic niacin extended-release tablets prior to the latest expiration date of the '428 patent and the '035 patent, including any extensions and/or additional periods of exclusivity to which Abbott is or becomes entitled.

e) Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Respectfully submitted,

MILLER, CANFIELD, PADDOCK AND STONE, P.L.C.

By: s/Thomas W. Cranmer
Thomas W. Cranmer (P25252)
Attorneys for Plaintiffs
840 West Long Lake Road, Suite 200
Troy, MI 48098-6358
Telephone: (248) 267-3381
cranmer@millercanfield.com

Dated: February 16, 2010

OF COUNSEL:

William F. Lee
Hollie L. Baker
Vinita Ferrera
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109

17,709,664.1\144432-00001